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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,937	10/25/2001	Christopher R. Ralph	1759.17239-FOR	8882

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EXAMINER

RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/001,937

Applicant(s)

RALPH ET AL.

Examiner

Anu Ramana

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-7,9-13 and 15-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-7,9-13 and 15-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/4/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 5, 6 and 7 are objected to because of the following informalities. Appropriate correction is required. In claim 5 (line 13), claim 6 (line 9) and claim 7 (10), "for expansion through the opening" must be amended to differentiate between the distal opening and the opening in the side wall to avoid confusion.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 16 and 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 7, line 7, "the bore being solid between.....cannula," renders the claims vague and indefinite because a bore cannot be solid. It appears that the Applicants are trying to claim that the bore terminates at the distal terminus of the opening. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Poddar (US 5,102,413).

Poddar discloses a rod or cannula 1 including a bore and an opening 13 in a sidewall and a bladder or "expandable structure" 2 for expansion through the opening from within the bore (Figs. 2 and 3 and col. 3, lines 24-68).

Claims 5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Berger (US 5,545,136).

Berger discloses a cannula 12 with a lumen or "internal bore" 16 and an open groove or "opening" 23 in a side wall of the cannula wherein a balloon catheter 24 has been mounted and secured (Figs. 1 and 6, col. 3, lines 40-67 and col. 4, lines 1-2).

With regard to the cannula "being sized and configured to establish a path into bone," it has been held that the recitation that an element is adapted or configured to perform a function is not a positive limitation but only requires the ability to so perform and does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. In the instant case the Berger cannula can be placed through a bore formed in bone thereby establishing a path into bone.

Claims 5 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Osorio et al. (US 6,726,691).

The applied reference has a common assignee and inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Osorio et al. disclose a cannula 600a having a side wall with an opening 700 in a side wall and an expandable structure 710 for expansion from within the bore through opening 700 (Fig. 18 and col. 16, lines 17-49).

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Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Makower et al. (US 5,380,290).

Makower et al. disclose a body access device or cannula 14 having a slotted opening 26 along a sidewall to facilitate placement of a catheter such a balloon catheter in a body (Figs. 1, 9 and 10, col. 1, lines 6-12, col. 2, lines 40-47 and col. 6, lines 23-68).

With regard to the cannula "being sized and configured to establish a path into bone," the bore "to accommodate passage of a guide pin," and the expandable structure "for treating bone adaptedbore," it has been held that the recitation that an element is adapted or configured to perform a function is not a positive limitation but only requires the ability to so perform and does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berger (US 5,545,136), as applied to claims 5 and 7, in view of Lombardo (US 6,488,653).

Berger discloses all elements of the claimed invention except for radiopaque markers.

Lombardo teaches radiopaque markers placed on a balloon for fluoroscopic visualization of the balloon (Figs. 5 and 6, col. 2, lines 41-50 and col. 5, lines 31-63).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided radiopaque markers on the balloon in the device of the combination of Berger and Lombardo for fluoroscopic visualization.

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Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being obvious over Osorio et al. (US 6,726,691), as applied to claims 5 and 7, in view of Lombardo (US 6,488,653).

The applied reference has a common assignee and inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Osorio et al. discloses all elements of the claimed invention except for radiopaque markers.

Lombardo teaches radiopaque markers placed on a balloon for fluoroscopic visualization of the balloon (Figs. 5 and 6, col. 2, lines 41-50 and col. 5, lines 31-63).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided radiopaque markers on the balloon in the device of the combination of Osorio et al. and Lombardo for fluoroscopic visualization.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-13 and 21-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 6,726,691 (Osorio et al. or '691 herein) in view of Witt (US 4,842,585).

Claim 11 of '691 discloses all elements of the claimed invention except for the structure of the spinal needle.

Witt teaches a spinal needle with a bore 13 and opening 12 in a side wall for placement of a catheter (Fig. 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute a spinal needle as, for example, taught by the Witt reference for the needle of '691 wherein so doing would amount to mere substitution of one functionally equivalent structure for another within the same art and the selection of any of these structures would equally well in the claimed method.

Claims 17-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 6,726,691 (Osorio et al. or '691 herein) in view of Makower et al. (US 5,380,290).

Claim 11 of '691 discloses all elements of the claimed invention except for the structure of the spinal needle.

Makower et al. disclose a body access device or cannula or "spinal needle" 14 having a slotted opening 26 along a sidewall for placement of an elongated element

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such as a catheter in a body (Figs. 1, 9 and 10, col. 1, lines 6-12 and col. 6, lines 23-68).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute a body access device as, for example, taught by Makower et al., for the spinal needle of claim 11, to facilitate placement of the balloon catheter.

The method steps of claims 17-20 are rendered obvious by the above discussion.

Response to Arguments

Applicants' arguments submitted under "REMARKS" in the response filed on January 14, 2005 have been considered but are moot in view of the new grounds of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR *Anu Ramana*
April 15, 2005

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